

**ASX ANNOUNCEMENT**  
**2 March 2010**

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## **BNC210 Clinical Trial Results Confirm Safety and Indicate Reduced Stress Hormone Levels**

- **BNC210 reduced blood levels of stress hormone in trial subjects, indicating anxiolytic activity**
- **Stage 2 of trial confirms BNC210 is safe and well tolerated**
- **Supports potential for once a day oral administration of BNC210**

**2 March 2010; Adelaide, Australia:** Bionomics Limited (ASX: BNO) today announced the final results of its Phase Ia clinical trial of BNC210.

Dosing of healthy male volunteers in stage 2 of the Phase Ia trial, which was conducted at the Pain and Anaesthesia Research Clinic (PARC) within the Royal Adelaide Hospital, was completed on schedule at the end of last year.

The primary objectives of the trial, to evaluate the safety, tolerability and the pharmacokinetics of BNC210 were met when stage 1 trial results were reported on 27 October 2009. Stage 1 of the trial evaluated a dose range of 5mg to 1200mg.

Evaluation of the safety and tolerability of BNC210 in stage 2 of the trial, in which subjects received either 2000mg of BNC210 or placebo, confirmed that BNC210 is safe and well tolerated at high dose levels.

In addition to safety and tolerability, stage 2 of the trial also involved an evaluation of blood cortisol levels. This evaluation showed that lower cortisol levels were observed in subjects receiving BNC210 compared to placebo. As anxiety and stress lead to an elevation of cortisol, the observed change following BNC210 administration is consistent with anxiolytic activity, and suggests that blood levels of this stress related hormone may be useful as a biomarker of BNC210 activity.

Stage 2 of the trial also enabled an extension of pharmacokinetic data which indicated that a plateau of absorption of BNC210 was observed at doses between 600mg and 1200mg.

The Principal Investigator on the trial Paul Rolan, Professor of Clinical Pharmacology at the University of Adelaide and a co-founder of PARC, commented "The first clinical testing of BNC210 in man has made important progress and under the conditions of this trial BNC210 has been shown to be safe and well tolerated. The most common reported side-effects which are possibly related to the drug were fatigue and headache, however these were quite mild".

Professor Rolan further commented "The second stage of the Phase Ia trial has yielded interesting data on blood cortisol levels. Anxiety and stress lead to an elevation of cortisol and subjects treated with BNC210 showed lower levels of cortisol in their blood. This finding, which will require further confirmation, may enable cortisol and potentially other neuroendocrine hormones to be used as biomarkers of BNC210 activity".

Dr Deborah Rathjen CEO & Managing Director of Bionomics said “We are very pleased with the outcome of this trial as we now have de-risked the BNC210 program with the data coming out of the study confirming that BNC210 is safe and has a pharmacokinetic profile which supports once a day administration. This trial has also given us an insight into biomarkers indicative of anxiety such as cortisol which will be followed up in the planned Phase Ib clinical trial and which provide valuable information for the BNC210 licensing package”.

Further details of the trial and its results are shown below in the Clinical Appendix.

BNC210 is being developed for the treatment of anxiety and co-morbid depression.

Anxiety is a common debilitating condition that affects 40 million patients over the age of 18 years in the US alone, and has an estimated market value of up to US\$15 billion worldwide.

Depression is a common mental disorder that presents with depressed mood, loss of interest or pleasure, feelings of guilt or low self esteem, disturbed sleep or appetite, low energy and poor concentration. Each year an estimated 6% of adult Australians are affected by a depressive illness. According to the World Health Organisation, depression affects an estimated 121 million people worldwide.

The global antidepressant market reached sales of almost US\$11 billion in 2008, with drugs such as Cymbalta (US\$2.7B), Effexor, which is also used for the treatment of generalized anxiety disorder (US\$3.9B), and Lexapro (US\$2.29B) being the primary drug treatments.

**FOR FURTHER INFORMATION PLEASE CONTACT:**

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**Clinical Appendix**

Phase I Protocol BNC210.001. The Pharmacokinetics and Clinical Tolerability of Ascending Single Doses of BNC210 in Healthy Volunteers	
Study Design	A double-blind placebo-controlled ascending single dose design in healthy volunteers
Primary Objective	To determine the pharmacokinetics of BNC210 and to determine the general clinical tolerability of ascending single doses of BNC210.
Secondary Objective	To determine the effects on Bond and Lader visual analogue scales rating neurological and psychiatric symptoms.
Key Assessments	Pharmacokinetics, adverse events, standard laboratory parameters, cortisol (2000 mg dose only), Bond and Lader visual analogue scales.
Study Population	Healthy male volunteers aged 18-65
Study Centre	Pain and Anaesthesia Research Clinic (PARC), Royal Adelaide Hospital
Treatment and Regimens	Ascending single doses of BNC210 from 5 to 2000 mg; placebo
Number of Participants	Eight cohorts of 4 participants, 3 will be randomized to receive BNC210 and one placebo.
Route of Administration	Oral, 10-20 mL of liquid suspension

Dose in Man (mg)	cMAX (ng/mL)	AUC (hr*ng/ml)
5	42	178
15	115	502
50	248	1395
150	254	1969
300	300	2479
600	726	5594
1200	801	6775
2000	855	5220

Rat PK studies have shown that an oral dose of 5 mg/kg achieves a C<sub>MAX</sub> of 439 ng/ml and an AUC of 3417 hr\*ng/ml. The pharmacokinetic data obtained from the Phase I trial, indicates that similar exposure occurs in man at doses between 300 to 600 mg (Figure 1 below). As the minimum dose of BNC210 that consistently produces an anxiolytic effect in rat models is between 0.1 and 1 mg/kg, the plasma levels achieved in man are well within those that produce an anxiolytic effect in animal models.

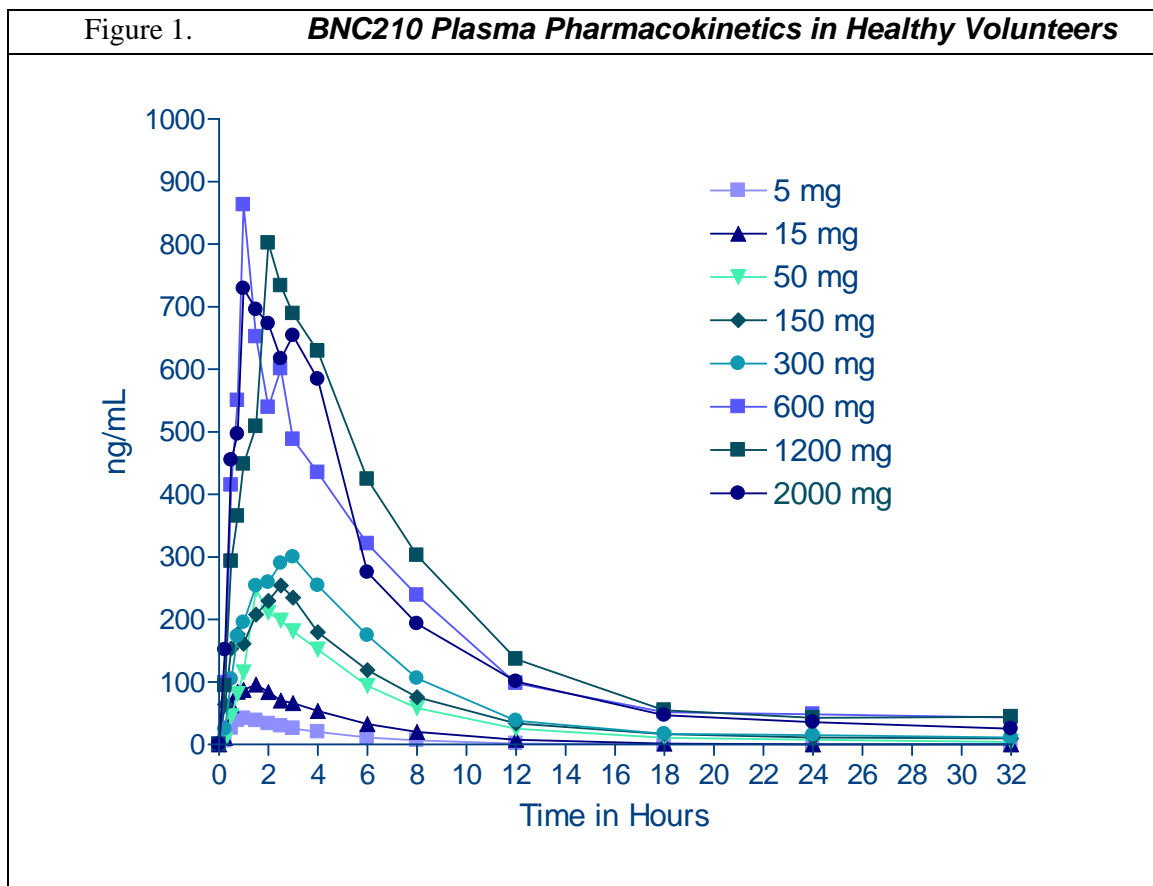
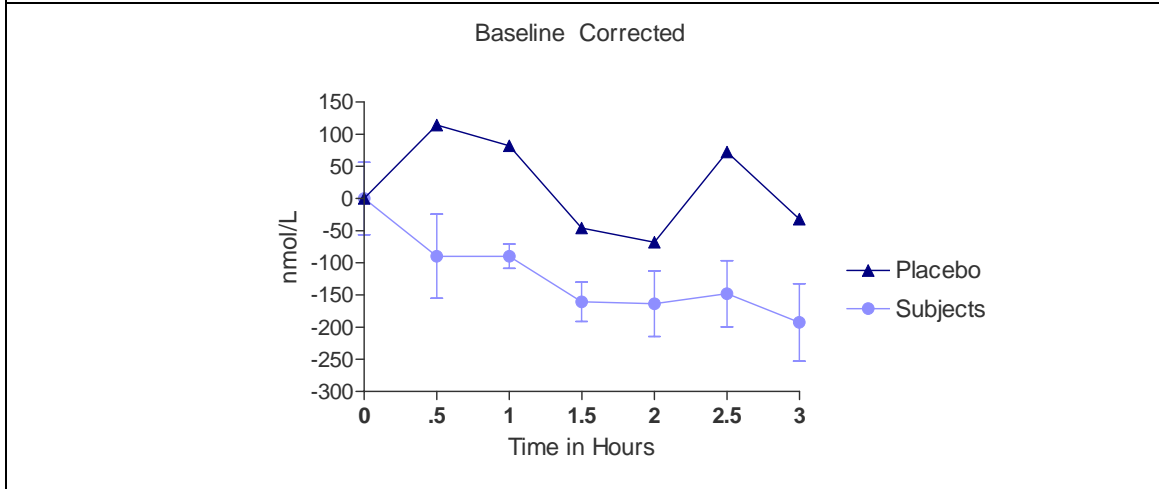


Figure 2.

### **Cortisol Levels in Healthy Volunteers Dosed with 2000mg of BNC210 Compared to Placebo**



#### **About Bionomics Limited**

Bionomics (ASX: BNO) discovers and develops innovative therapeutics for cancer and diseases of the central nervous system. Bionomics has small molecule product development programs in the areas of cancer, anxiety, epilepsy and multiple sclerosis. BNC105, which is undergoing clinical development for the treatment of cancer, is based upon the identification of a novel compound that potently and selectively restricts blood flow within tumours. A clinical program is also underway for the treatment of anxiety disorders based on BNC210 which exhibits strong anxiolytic activity without side effects in preclinical models. Both compounds offer blockbuster potential if successfully developed.

Bionomics' discovery and development activities are driven by its three technology platforms: Angene®, a drug discovery platform which incorporates a variety of genomics tools to identify and validate novel angiogenesis targets (involved in the formation of new blood vessels). MultiCore® is Bionomics' proprietary, diversity orientated chemistry platform for the discovery of small molecule drugs. ionX® is a set of novel technologies for the identification of drugs targeting ion channels for diseases of the central nervous system.

For more information about Bionomics, visit [www.bionomics.com.au](http://www.bionomics.com.au)

#### **Factors Affecting Future Performance**

*This announcement contains "forward-looking" statements within the meaning of the United States' Private Securities Litigation Reform Act of 1995. Any statements contained in this press release that relate to prospective events or developments are deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "projects," "forecasts," "will" and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those indicated by these forward-looking statements, including risks related to the clinical evaluation of either BNC105 or BNC210, our available funds or existing funding arrangements, a downturn in our customers' markets, our failure to introduce new products or technologies in a timely manner, regulatory changes, risks related to our international operations, our inability to integrate acquired businesses and technologies into our existing business and to our competitive advantages, as well as other factors. Subject to the requirements of any applicable legislation or the listing rules of any stock exchange on which our securities are quoted, we disclaim any intention or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.*